UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/781,055	02/18/2004	Stephen Johnston	UTSD:788US	9475

32425 7590 10/31/2006

FULBRIGHT & JAWORSKI L.L.P.
600 CONGRESS AVE.
SUITE 2400
AUSTIN, TX 78701

EXAMINER	
MCGILLEM, LAURA L	
ART UNIT	**PAPER NUMBER**
1636	

DATE MAILED: 10/31/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/781,055	JOHNSTON ET AL.	
	Examiner	Art Unit	
	Laura McGillem	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 August 2006*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2-20,22 and 24-35* is/are pending in the application.

4a) Of the above claim(s) *22 and 24-35* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

It is noted that claims 2, 6 and 15 have been amended, claims 1 and 21 have been canceled and claims 22-35 have been withdrawn in the amendment filed 8/17/2006. Claims 2-20 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 6 and 15-20 have been newly added to this rejection because of the amendment to change their dependency. Claims 7-20 are indefinite insofar as they are dependent on an indefinite claim.

Applicant's arguments, see REMARKS page 14, filed 8/17/2006, with respect to the rejection of claim 2 under 35 U.S.C. § 112, second paragraph have been fully considered and are persuasive. The rejection of claim of 2 regarding the word "initiator" has been withdrawn.

Claims 2-5 are vague and indefinite because they recite the phrase "downstream promoter element" and "upstream binding element" and as the claim is written, it does not recite a gene operably linked to the claimed elements, therefore it is not clear what is meant by "downstream" or "upstream". Claims 2-5 are vague and indefinite because they recite the phrase "upstream binding element" and it is not clear to what the binding

element binds. As the claim is written, an "upstream binding element" is a binding element to which "upstream" binds.

This rejection is being maintained for reasons given in the Office action mailed 4/14/2006 and for reasons outlined below.

Applicants submit that the phrases "downstream promoter element" and "upstream binding element" are definite. Applicants submit that the Action is viewing "downstream" and "upstream" as describing a positional relationship of the downstream promoter element and upstream binding element to a gene operably linked to these elements. Applicants submit that a proper evaluation under the second paragraph of 35 U.S.C. § 112 requires that the claim be read in light of the specification as interpreted by one of ordinary skill in the art. Applicants submit that the specification (page 26, lines 10-19) provides an exemplary synthetic promoter construct that was centered by a TATA box with the initiator at position +1 and with various binding sites and other elements added upstream and downstream of the TATA box. Applicants submit that the "downstream promoter element" refers to a particular type of promoter element described by Burke et al. (see e.g., Specification, Table 1, and p. 27, In. 29), and which was named the downstream promoter element because it was first identified downstream of the RNA start site. Applicants submit that in Example 8 of the specification, the placement of downstream element is described relative to the initiator sequence (p. 31, In. 9-21). Applicants submit that the recitation of an operably linked gene is not necessary to understand the meaning of the term "downstream promoter element." Applicants submit that the term "upstream binding element" refers to an

element located upstream of the core promoter region, i.e., the TATA box (Specification, p. 32, In. 7-12). Applicants submit that examples of upstream binding elements provided in the specification include the IRF, SP1, CBP, NFκB, AP1, and IFN binding elements (Specification, p. 4, In. 10-18; p. 32, In. 9). Applicants submit that citations to publications describing these binding elements may be found in Table 1 of the specification. Further, Applicants submit that the Action's further assertion that an "upstream binding element" refers to a binding element to which "upstream" binds is unsupported by any reasoning and is inconsistent with the meaning of the this term to a person of ordinary skill in view of the disclosure in the specification.

Applicants' arguments filed 8/17/2006 have been fully considered but are not persuasive. The terms downstream and upstream are relative terms, and while the specification teaches that the "downstream promoter element" refers to a particular type of promoter element which was named the downstream promoter element because it was first identified downstream of the RNA start site, the disclosure does not specifically define "downstream promoter element". The exemplary synthetic promoter construct that was centered by a TATA box with the initiator at position +1 and with various binding sites and other elements added upstream and downstream of the TATA box does not limit the claimed nucleic acid segment and merely provides an example of a "downstream promoter element". As the claims are written, it is not clear that the TATA box is the center of the construct so that the skilled artisan would know that the other elements are to be placed relative to the TATA box. Applicants submit that the placement of downstream element is described relative to the initiator sequence in

Example 8 of the specification (p. 31, In. 9-21) and provide an exemplary downstream element nucleic acid sequence. Again as the claims are written, it is not clear that the initiator sequence is the center of the construct so that the skilled artisan would know that the Applicants intend that the other elements are to be placed relative to the initiator sequence.

Although Applicants submit that the term "upstream binding element" refers to an element located upstream of the core promoter region, i.e., the TATA box, as the claims are written, it is not clear that the TATA box is the center of the construct so that the skilled artisan would know that the other elements are to be placed upstream relative to the TATA box. Description in the specification of a binding sites located upstream of the core part of the promoter merely provides non-limiting examples of "upstream promoter elements". It is not clear what the Applicants intend to be the core part of the promoter, so that the skilled artisan would know where would be considered an "upstream promoter element".

Although Applicants submit that the Action's further assertion that an "upstream binding element" refers to a binding element to which "upstream" binds is unsupported by any reasoning and is inconsistent with the meaning of the this term to a person of ordinary skill in view of the disclosure in the specification, it is not clear what would be binding to an upstream binding element so that the skilled artisan would know whether a nucleic acid segment would meet the limitations of the claim. For example, the phrase "CBP Binding Element" refers to a segment of a nucleic acid segment to which the

protein CBP can bind. The phrase "upstream binding element" does not clarify the metes and bounds of what binds to the element located "upstream".

Claims 5-6 are vague and indefinite because they recite the phrase "CBP binding element" and the acronym "CBP" appears to denote multiple proteins in the art, including CREB binding protein, cAMP binding protein and CAT binding protein. It is not clear which protein is meant by "CBP".

This rejection is being maintained for reasons given in the Office action mailed 4/14/2006 and for reasons outlined below.

Applicants submit that as indicated in the present specification, the CBP binding element refers to the CBP binding element reported by Graves et al. (see e.g., Specification, Table 1). Applicants submit that in view of the present specification, a person of ordinary skill in the art would understand that "CBP" denotes "CAT binding protein."

Applicants' arguments filed 8/17/2006 have been fully considered but are not persuasive. Table I lists only CBP with the reference for Graves et al. The skilled artisan would not know what the Applicant intends CBP to represent since Table I is merely a listing of binding elements.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 2-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Applicants claim a nucleic acid segment comprising a synthetic promoter enhancer or the complement of such a promoter enhancer, comprising a TATA box, a TFIIB binding element, an initiator, a downstream promoter element and upstream binding element. Applicants claim a nucleic acid segment further encoding an immunogenic peptide or polypeptide such as HIV gp120 for use in a genetic immunization vector for a pharmaceutical composition.

The written description requirement for a genus may be satisfied by sufficient description of a representative number of species by actual reduction to practice or by disclosure of relevant identifying characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show that applicant was in possession of the claimed invention.

In the instant case, the nucleic acid segment comprising a synthetic promoter/enhancer as claimed encompasses a very broad genus of downstream promoter elements and upstream binding elements. The specification discloses three sequences (SEQ ID NOs:35-37) for the claimed promoter sequence. The specification does not describe, exemplify or measure activity of a promoter sequence or a

complement of a promoter sequence other than SEQ ID NOs:35-37. There is no description of any mutational sites that naturally occur in the promoter/enhancer and there is no description of how the structure of the disclosed SEQ ID NOs:35-37 relates to the structure of any other promoter enhancer with broadly claimed downstream promoter elements and upstream binding elements. The genus would be expected to have divergent functional properties as small changes in sequences can have significant effects on function. The specification does not provide an indication of how the sequences of SEQ ID NOs:35-37 are representative of other promoter/enhancers sequences or the complement of promoter/enhancers sequences. The specification has not described whether a promoter/enhancer or a complement of a promoter/enhancer comprising any of a large group of possible downstream promoter elements or upstream binding elements would be sufficient as a promoter for any immunogenic polypeptide, including HIV gp120, so that it could be used as a pharmaceutical composition. According to these facts, one of skill in the art would conclude that applicant was not in possession of the claimed genus because a description of only one member of this genus is not representative of the variant of the genus and is insufficient to support them.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 2, 6, 15 and 17-19 are rejected under 35 U.S.C. 102(b) as being anticipated by Matthews et al (U.S. Patent 5,717,058, 2/10/1998). This is a NEW Rejection.

Matthews et al teach regulators of gene transcription and methods of modulation of gene expression at the transcription level through the modulation of protein-protein interactions that regulate transcription (see column 12, lines 60-65, for example). Matthews et al teach that RNA polymerase II requires associated general initiation factors such as TFIIB to bind to promoter DNA (see column 21, lines 47-52, for example). Matthews et al teach that host proteins can help activate transcription indirectly through certain DNA sequence elements including the cAMP response element (CRE) and an NFκB element (see column 22, lines 12-17, for example). Matthews et al teach that other auxiliary host proteins include AP1, Sp1, NFκB and TFIIB (see column 23, lines 24-26, for example). Matthews et al disclose that suitable target sequences for transcription regulation can include DNA sequences upstream, downstream or within the coding region. Preferably there are Tax responsive elements

such as (TxRE) in an HTLV-LTR promoter, including an NFκB element or ATF/CREB, as well as promoters not responsive to Tax (see column 23, lines 29-35).

Matthews et al teaches that enhancer regions are important in optimizing gene expression and are generally sequences found upstream of the promoter region (see column 37, lines 45-50, for example). Matthews et al teach an *in vitro* transcription assay using nuclear extracts containing RNA polymerase II and sequence specific DNA binding proteins. Matthews et al teach a promoter comprising NFκB binding sites, Sp1 and CRE response elements (i.e. an upstream binding elements), a 21 bp repeat binding protein, a TATAA box, and an initiator element). Since the instant specification does not provide a specific limiting definition of downstream promoter element, the 21 bp repeat binding protein anticipates a downstream promoter element. The promoter elements taught by Matthews et al anticipate a nucleic acid segment comprising a synthetic promoter enhancer comprising regions including a TATA box, an initiator, and upstream binding element and a TFIIB binding element as claimed in claim 2.

Matthews et al teach an embodiment in which the HTLV-LTR promoter is upstream of a luciferase gene or an RSV LTR is upstream of the CAT gene (see column 28, lines 1-10, for example), which meets the limitation of claim 15, wherein a nucleic acid segment encodes or potentially encodes an immunogenic peptide or polypeptide. Matthews et al teach that the promoter can be cloned into pGL2-basic vector (see column 24, lines 39-42, for example), which reads on a nucleic acid that encodes or potentially encodes an immunogenic peptide, or polypeptide in a linear or circular expression vector that is a plasmid as in claims 15 and 17-19.

Claims 2, 6-11, 15 and 17-20 are rejected under 35 U.S.C. 102(a) as being anticipated by Parks et al (U.S. Patent Application Publication No. 2002/0055173, 5/9/2002). This is a NEW Rejection.

Parks et al teach an adenovirus type 5 major late promoter (MLP) in which the transcription factors known as MAZ and Sp1 can interact with GC-rich sequences flanking the TATA box. Parks et al teach that two MAZ binding sites are centered at -18 and –36 relative to the transcriptional initiation site. SP1 binds only to the –18 GC-rich sequence (see abstract, paragraphs 004-005, 0021 and 0073, for example). Parks et al teach that there are a number of transcription binding sites in the MLP promoter including the TATA box binding element, the USF/MLTF binding site at –50, a CAAT box near –70, and initiator site at +1 and downstream elements that bind to cellular factors and a viral IVa2 protein (see paragraphs 0003, 0015, 0063 and 0080, for example), which reads on a promoter comprising a TATA box, an initiator, a downstream promoter element and upstream binding elements wherein the upstream binding element is a SP1 binding element, as claimed in claim 2 and 6. Parks et al teach that when the protein complex of TFIID/TFIIA/TFIIB interacts with the promoter, TFIIA and TFIIB contact the promoter both upstream and downstream of the TATA sequence, which reads on a promoter with a TFIIB binding element.

The instant specification does not provide a specific definition of the phrase "spacer region" except that it would be between two or more regions encoding a

promote or enhancer binding element. Parks et al illustrate a portion of the promoter in Figure 2 C. Absent evidence to the contrary, the nucleotides GCTA at nucleotides –177 to –174 upstream of the MAZ/SP1 binding region is a spacer region between the MAZ/SP1 and IVa2 binding sites that does not bind protein, with an approximately equal distribution of adenine, guanine, cytosine and thymine bases to meet the limitations of claims 7-9. Absent evidence to the contrary, the nucleotides TTT at nucleotide position –76 to –74 upstream of the MAZ/TATA/Maz/SP1 binding site and downstream of the MAZ binding element is a spacer region that does not bind protein, comprising three consecutive thymine bases to meet the limitations of claims 7-8 and 11. Absent evidence to the contrary, the nucleotides AAA-206 at nucleotide position -206 to -208 upstream of the Maz/SP1 binding site and downstream of the IVa2 binding element is a spacer region that does not bind protein, comprising three consecutive adenine bases to meet the limitations of claims 7-8 and 10.

Parks et al teach that this inventive promoter can be used in a vector for the expression of therapeutic proteins (see paragraph 0002, for example). Parks et al teach that the MLP promoter can be linked to a gene encoding luciferase in a reporter plasmid (see paragraphs 0017, for example), which anticipates claims 15 and 17-19 as a nucleic acid segment encoding or potentially encoding an immunogenic peptide or polypeptide in a circular expression element that is a plasmid vector. Parks et al teach that this inventive promoter can be used in an adenovirus based vector with a non-adenovirus based DNA for use as a pharmaceutical composition for gene therapy, such as antisense RNA sequences, therapeutic ribozymes (see paragraph 0039, 0043, for

example) which reads on the limitations of claims 15 and 17- 20 as a nucleic acid segment encoding or potentially encoding a immunogenic peptide or polypeptide in a circular or linear viral vector.

Claims 2, 15 and 17-19 are rejected under 35 U.S.C. 102(e) as being anticipated by Roninson et al (U.S. Patent Application Publication No. 2003/0186424, filed 08/29/2002). This is a NEW Rejection.

Roninson et al teach recombinant expression constructs encoding reporter genes operably linked to core promoters from genes that are induced by p21 (see paragraphs 0004 and 0013, for example). Roninson et al teach that the promoters comprise TATA box regions (see paragraph 0022, for example). Roninson et al teach that a core promoter encompasses a sequence required for transcription initiation and comprises a region for about –46 to about +17 as measured from the transcription initiation site (see paragraph 0033, for example). Roninson et al also teach that the TATA box is flanked on the downstream side by an extended A/T rich sequence and on the upstream side by a G/C rich region (see paragraphs 0047 and 0080, for example). Roninson et al teach an alignment of hybrid core promoter comprising AdML and Bax TATA boxes and initiator elements, and teach that some of the promoters are of different lengths because of variations in spacing between the TATA boxes and initiator elements (see paragraph 0024, for example). Roninson et al teach that the TBP/TFIIB complex binds to the AdML TATA box but not the Bax TATA box (see paragraphs 0026 and 0082-0083, for example). Roninson et al teach that p21 inducibility is determined by factors

binding the upstream promoter (i.e. upstream binding element) (see paragraph 0027, for example). Therefore, the promoter taught by Roninson et al comprises a transcription initiation site, TATA box region, binding for a TFIIB complex, a binding element for a upstream promoter and a downstream promoter element in the form of an extended A/T rich sequence which anticipates the nucleic acid segment of claim 2.

Roninson et al further teach recombinant expression vectors that are preferably viral vectors (see paragraph 0038, for example). Roninson et al exemplify that a core promoter region was inserted in a pGL3-basic luciferase reporter plasmid and five GAL4 DNA binding sites were inserted upstream of the core promoter (see paragraph 0062, for example). Absent evidence to the contrary, the luciferase gene potentially encodes an immunogenic polypeptide which anticipates the limitations of claims 15 and 17-19 wherein the nucleic acid segment encodes or potentially encodes an immunogenic polypeptide and is a linear or circular expression vector that is a plasmid or viral vectors.

Claims 2, 15 and 17- 20 are rejected under 35 U.S.C. 102(e) as being anticipated by (Price) U.S. Patent 7,018,836, filed 10/15/1997 (of record). This is a NEW Rejection.

Price teaches nucleic acids related to the control of transcription comprising a recombinant promoter that direct expression of a transcription elongation factor P-TEFb (see column 13, lines 40-55, column 45, lines 56-67). Price discloses that the promoter functions as a start site for RNA synthesis and includes a TATA box and promoter elements upstream and downstream of the transcription start site (see column 47, lines 30-50, for example). Price also teach an assay that reveals that the presence of at least

transcription factor TFIIB was required for transcription elongation (see column 84, lines 1-13, in particular) showing that a TFIIB binding element would be inherent in the promoter sequence requiring the presence of TFIIB for function. The teachings of Price read on a nucleic acid segment comprising a promoter sequence comprising regions encoding promoter elements including a TATA box, a TFIIB binding element, and initiator, a downstream promoter element and an upstream binding element (claim 2).

Price teaches that preferable regions of P-TEFb will be those containing immunogenic sites and can be used for vaccination in combination with an immunogenic carrier protein (see column 58, lines 17-20 and column 60, lines 31-35, for example), which reads on the claimed nucleic acid segment encoding or potentially encoding an immunogenic P-TEFb peptide in a pharmaceutical composition as claimed in claim 15 and 20. Price teaches that preferable expression vectors include adenoviral vectors, plasmid vectors and phage vectors (see column 56, lines 23-25, for example), which meet the limitations of claims 17-19.

Claims 2 and 15-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Krohn et al (U.S. Patent Application Publication No. 2003/0129169, filed 5/3/2002) as evidenced by Matthews et al (U.S. Patent 5,717,058, 2/10/1998). This is a NEW Rejection.

Krohn et al teach plasmid and viral DNA vaccines and gene therapeutics comprising novel vectors comprising a cloning site for a gene of interest and a strong viral promoter in order to drive the expression of the gene of interest (see Abstract and

paragraph 0009, for example). Krohn et al teach that the expression cassette comprises enhancer/promoter sequences that enable expression of the gene of interest and include binding sites for RNA polymerase. Krohn et al does not specifically teach that the promoter would require a TFIIB binding element, but Matthews et al teach that RNA polymerase II requires associated general initiation factors such as TFIIB to bind to promoter DNA (see column 21, lines 47-52, for example). Therefore, if the promoter taught by Krohn et al comprises binding sites for RNA polymerase then it would inherently have a binding site for TFIIB. Krohn et al teach that other regulatory regions include sequences involved with initiation of transcription, such as a TATA box, a capping sequence and a CAAT sequence. Further, the 3' non-coding region can comprise transcription termination regulatory sequences (see paragraph 0197, for example). The instant specification does not provide a limiting definition of a downstream promoter element or an upstream binding element. Therefore the 3' transcription termination regulatory sequences reads on a downstream promoter sequence and the CAAT sequence reads on an upstream binding element. The teaching of Krohn et al anticipates a nucleic acid segment comprising a synthetic promoter/enhancer comprising a TATA box, an initiator, an upstream binding element and downstream promoter element as claimed in claim 2.

Krohn et al teach an embodiment of the invention in which the gene of interest is HIV gp120/gp160 (see paragraphs 0059 and 0165, for example), which anticipates the limitation of a nucleic acid segment encoding a immunogenic peptide or polypeptide wherein the immunogenic polypeptide is HIV gp 120. The plasmid and viral DNA

vaccines and gene therapeutics comprising novel vectors comprising HIV gp 120 gene and a strong viral promoter (see paragraph 0085, for example) anticipates the nucleic acid segment in a pharmaceutical composition as a linear or circular plasmid or viral vector as in claims 15-20.

Claims 2-3, 15 and 17-20 are rejected under 35 U.S.C. 102(e) as being anticipated by Berger (U.S. Patent Application Publication No. 2003/0104356, filed 3/26/2002) as evidenced by Matthews et al (U.S. Patent 5,717,058, 2/10/1998). This is a NEW Rejection.

Berger teaches a promoter sequence capable of binding an RNA polymerase and initiating transcription. Berger teaches that the promoter sequence comprises a translation start codon, an initiator, protein binding domains responsible for binding of RNA polymerase, a TATA box or a CAAT box, Shine Delgarno sequences, –10 and –35 consensus sequences. Berger also teaches upstream regulatory control sequences and enhancers which provide for the transcription and translation of a coding sequence in a host cell (see paragraphs 0056-0057, for example). It is noted that the instant disclosure does not provide a specific definition of downstream promoter sequence, therefore the –10 consensus sequence can be considered a downstream promoter sequence. Berger does not specifically teach that the promoter would require a TFIIB binding element, but Matthews et al teach that RNA polymerase II requires associated general initiation factors such as TFIIB to bind to promoter DNA (see column 21, lines 47-52, for example). Therefore, if the promoter taught by Berger comprises binding sites for RNA

polymerase then the promoter would inherently have a binding site for TFIIB. The promoter sequence taught by Berger comprises a TATA box, a TFIIB binding element, and initiator, a downstream promoter element and an upstream binding element and meets the limitations of claim 2. Berger teaches that transcription of IFN-β modulated by multiple regulatory factors that bind upstream of the initiation site, such as the activators IRF-1 and NFκB (see paragraphs 0028 and 0084, for example), which reads on a promoter sequence comprising an upstream IRF binding element (claim 3).

Berger teaches an embodiment of the invention using a polypeptide with a pharmaceutically acceptable carrier for therapeutic or prophylactic purposes such as for a vaccine (see paragraphs 0021 and 24, for example). Berger teaches use of plasmids, phages or cosmids, which reads on a linear or circular expression element such as a genetic immunization vector, phagemid, cosmid or plasmid vector (see paragraphs 0047 and 0053), which meets the limitations of claims 17-20. Berger teaches that a polypeptide expressed from a vector comprising said promoters can be used as an antigen or immunogen for vaccination or as a component in a DNA vaccine (see paragraphs 0134-0137, in particular), which reads on a nucleic acid segment encoding an immunogenic peptide or polypeptide as claimed in instant claim 15.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura McGillem whose telephone number is (571) 272-8783. The examiner can normally be reached on M-F 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Laura McGillem, PhD
10/26/2006

DANIEL M. SULLIVAN
PATENT EXAMINER